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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,587	01/15/2002	Nabil L. Muhanna	M112 1100	4693
7590 10/20/2004 WOMBLE CARLYLE SANDRIDGE & RICE P.O. Box 7037 Atlanta, GA 30357-0037			EXAMINER STOKES, CANDICE CAPRI	
			ART UNIT 3732	PAPER NUMBER
DATE MAILED: 10/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/047,587

Applicant(s)

MUHANNA, NABIL L.

Examiner

Candice C. Stokes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-8, 10, 11, 14, 15, 17, 18, 20, 24, 26-30 and 32-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6, 7, 27, 30, 32 and 46 is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 10, 11, 14, 15, 17, 18, 20, 24, 26, 28, 29, 33-40 and 42-45 is/are rejected.
- 7) ☒ Claim(s) 41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-2, 14, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Monson (USPN 4,863,477). Monson discloses an intervertebral disc prosthesis 2. “The synthetic disc is molded of a biologically compatible, non-porous rubber, silicone-rubber or synthetic plastic material each having a hollow, molded interior which, when joined together with a non-toxic adhesive, for, a body having a fluid-tight cavity” (col.2, lines 39-44). The body is inherently compressible because rubber is compressible. As to Claim 28, it is inherent that any foreign object must be sterilized before implantation into the body.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Monson in view of Gauchet (USPN 6,395,032). Monson discloses the claimed invention except for the body of the prosthesis made of a laminate comprising a plurality of layers. Gauchet’s invention “provides an intervertebral disc prosthesis comprising a compressible cushion having a body made of a material, and a liquid which is able to come into contact with the body” (column 1,

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lines 47-49). "The prosthesis has a cushion 14 interposed between the plates 4. This cushion comprises bellows or folded laminate sheets 16. It would have been obvious to one having ordinary skill in the art at the time of the invention to make the body of the prosthesis from a laminate as taught by Gauchet, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

2) Claims 8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monson in view of Boyer, II (US 2001/0039458 A1). Monson discloses the invention as stated in Claim 8 except for the biocompatible material selected from a dissected animal and the dissected animal tissue selected from porcine and bovine tissue. As to Claim 10 Kuntz does not disclose the biocompatible material fixed by a protein cross-linking agent, in particular glutaraldehyde. Boyer, III et al teach a variety of bone grafting materials "another bone-grafting material is disclosed in US Pat. No. 4,678,470 to Nashef et al., and is formed using a tanning procedure involving glutaraldehyde that renders the material osteoconductive. A bone block is shaped into a precise predetermined form and size using conventional machining techniques. A paste-like suspension is also formed using known methods of comminuting bone, such as milling, grinding, and pulverizing, and adding the pulverized or powdered bone to a carrier. The treatment of glutaraldehyde allows the use of bovine, ovine, equine, and porcine bone sources. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the tissue of a bovine as well as the protein cross-linking agent as taught by Boyer, III et al in order to provide a prosthesis that stimulates bone growth manufactured from a wider range of biocompatible tissue.

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3) Claims 15,17,18,20,34-38,40,43-45 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Monson in view of Kuntz (USPN 4,349,921). Kuntz discloses, “one embodiment of the intervertebral disc prosthesis according to the invention is shown at 10 in FIGS. 1,2, and 3. The prosthesis 10 is formed of a thin block of biologically acceptable material having slightly convex superior and inferior surfaces 11 and 12, transverse grooves 13 in said superior and inferior surfaces and also in both lateral surfaces 14, 14, a flange or lip 15 raised from said superior and inferior surfaces at one longitudinal end of the prosthesis, and a wedge shaped tapering portion 16 at the other longitudinal end” (column 6, lines 9-18). This also anticipates Claim 15. As to Claim 14, the body has an anterior and posterior face. Furthermore, Kuntz teaches, “the wedge shaped tapering portion 16 allows for easier insertion of the prosthesis into the disc space” (column 6, lines 67-68). As to Claims 17-18, “the prosthesis 10 is essentially a spacer and can be fabricated from any biologically acceptable material of suitable strength and durability, for example high density polyethylene, polymethylmethacrylate, stainless steel, or chrome cobalt alloys”(column 7, lines 52-57). With regard to Claims 20 and 34-38, Kuntz teaches a method of maintaining intervertebral space between adjacent vertebrae is disclosed wherein “the diseased discs are excised anteriorly and the space is thoroughly curetted out, removing the whole of the disc” (column 10, lines 18-20). “Once the space has been well curetted out to the posterior aspects of the body and while traction is being applied to the neck by the anesthetist, the intervertebral disc prosthesis 10 is tapped into position” (column 10, lines 32-35). Specifically to Claim 36, the prosthesis disclosed by Monson consists of a silicone-based polymer. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide the thickness of the anterior face greater than that of the posterior face of the

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prosthesis, to provide the prosthesis spacer comprised of non-resilient material and to provide a method for using the prosthesis as taught by Kuntz in order to improve the prosthesis and provide a prosthesis more suitably dimensioned and shaped to replace a natural disc.

4) Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Monson in view of Ledergerber (USPN 6,187,043). Monson discloses the claimed invention except for a portion of the material is a ribbon. Ledergerber teaches an implantable prosthetic device where “in one embodiment, a complex woven PTFe filament or ribbon is sewn or affixed” (col. 3, lines 6-8). It would have been an obvious matter of design choice to fabricate a portion of the prosthesis from a ribbon, since applicant has not disclosed that such a material solves any stated problem or is for any particular purpose and it appears that the invention would perform equally as well without a portion being ribbon.

5) Claims 33 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monson in view of Kuntz in further view of Ledergerber. Monson and Kuntz teach the method as described except for the body formed from a length of biocompatible, compressible, resilient ribbon. Ledergerber teaches an implantable prosthetic device where “in one embodiment, a complex woven PTFe filament or ribbon is sewn or affixed” (col. 3, lines 6-8). It would have been an obvious matter of design choice to fabricate a portion of the prosthesis from a ribbon, since applicant has not disclosed that such a material solves any stated problem or is for any particular purpose and it appears that the invention would perform equally as well without a portion being ribbon.

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***Allowable Subject Matter***

Claims 27,6-7,30,32, and 46 are allowed.

Claim 41 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Stokes whose telephone number is (703) 305-8128.

The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Candice C. Stokes



Cary E. O'Connor  
Primary Examiner